UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 1, 1998

MEMORANDUM:

SUBJECT: **Tribuphos.** Amendment: Animal Feeding Study Memorandum (DP Barcode: D220694. GLN 171-4(j). Chemical No. 074801. Case No. 2145).

FROM: Catherine Eiden, Chemist
Risk Characterization & Analysis Branch
Health Effects Division (7509C)

THRU: Steve Knizner, Branch Senior Scientist
Risk Characterization & Analysis Branch
Health Effects Division (7509C)

TO: Tom Luminello, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

BACKGROUND

The HED Chemistry Exposure Assessment Committee (Chem SAC) met on 3/18/98 to reconsider the use of cotton gin byproducts containing tribuphos residues in the dairy and beef cattle diet. During the meeting a related issue was also discussed. Specifically, whether or not to use residue data on cotton leaves taken from a cotton metabolism study (S. Funk, 11/23/93, D169854 & D179581) in the absence of field trial data for cotton gin byproducts to estimate tribuphos residues contributed to the animal diet from cotton gin byproducts. The Chemistry Chapter for the RED for this chemical included a data requirement for field trials on cotton gin byproducts. Those data have not been received to date. The Chem SAC was asked the following questions: 1) How much gin byproduct to include in the animal diets? and, 2) Could we use residue data on cotton leaves from the metabolism study?

The Chem SAC determined that 20% cotton gin byproduct should be included in the animal diets, and that 200 ppm should be used as a default value for residues of tribuphos on cotton gin byproducts based on the residue data on cotton leaves from the metabolism study. Twenty

percent gin byproduct in the diet represents a maximum (Table I, OPPT 860 Guidelines) of this commodity in the animal diet, and 200 ppm represents an interpolated value of tribuphos residues on cotton leaves 7 days after application of tribuphos at 3X the seasonal maximum application rate. The post-harvest interval (PHI) for this use of tribuphos on cotton is 7 days.

The table below provides the residue data for tribuphos on cotton leaves from the cotton metabolism study, in which a 3X maximum seasonal application rate of tribuphos was applied.

Table 1. Radioactivity Levels in Cotton Plant Parts After Treatment with ^{14}-C Tribuphos at 6.2 lbs. a.i./A

Matrix	Posttreatment Days	Tribuphos equivalents (ppm)
Seed (Delinted)	0	0.01
	3	0.07
	9	0.07[1]
Foliage	0	92.5[2]
	3	253[2,3]
	9	175[2]

1 Sum of results for extracts and residual solids. The registrant indicates that the seed prior to extraction was radioassayed, and calculations of expected radioactivity levels suggest that this is the case. 2 The registrant indicates that the foliage prior to extraction was radioassayed, and calculations of expected radioactivity levels suggest that this is the case. 3 Increase from day 0 attributed to loss of water from the foliage.

Based on the Chem SAC's recommendations a new theoretical 1X diet containing tribuphos residues has been calculated below:

Table 2. Theoretical Livestock Diet Containing Feedstuffs with Tribuphos Residues.

Feedstuff & Tribuphos Residue (ppm)	% DM	% Diet for Dairy (Maximum)*	Tribuphos Intake (ppm)	% Diet for Beef (Maximum)*	Tribuphos Intake (ppm)
Cottonmeal (4 ppm)**	89	10 (15)	0.45	10 (15)	0.45
Cotton gin byproducts (200 ppm)***	90	20 (20)	44.44	20 (20)	44.44
Total Dietary Intake (ppm)			45		45

* The value in parentheses is the maximum percentage of this feedstuff in the animal's diet according to Table I. ** The value in the parentheses is the tolerance level residue for cottonmeal. *** The value in the parentheses is the default value assumed for residues of tribuphos on cotton leaves from a plant metabolism study. The study used a 3X application rate of tribuphos.

The equation used to calculate the dietary intake of tribuphos residues in the animal's diet is: residue (ppm) x % feedstuff in diet ÷ % DM. Using the maximum percent of cotton gin

byproducts in the animal's diet as recommended by the Chem SAC, and 200 ppm of tribuphos residues on cotton leaves from the cotton metabolism study in lieu of field trial data on cotton gin byproducts, the animal's theoretical dietary intake of tribuphos is 45 ppm. This is used as the 1X feeding level. This affects the tolerance reassessment for meat and milk for tribuphos residues.

In the animal feeding study review (C. Eiden, 12/19/95, D220694), residues of tribuphos in milk were reported at a maximum of 0.15 ppm on day 14 after dosing the animal at 121 ppm (2.7X). Tribuphos residues were reported to be non-detectable (ND = <0.01 ppm) in all milk samples tested after dosing the animal at 33 ppm (0.7X). Extrapolating from the 2.7X feeding level to the 1X feeding level, residues of tribuphos in milk are expected to be as high as 0.008 ppm. The existing tolerance for tribuphos residues in milk is 0.002 ppm. Also, note the submitted enforcement method under reregistration for tribuphos residues in milk has a reported limit of quantitation of 0.01 ppm. The existing tolerance should be revoked. A tolerance of 0.01 ppm is recommended for milk.

Maximum tribuphos residues in animal tissues, meat, meat byproducts, and fat from animals dosed at 121 ppm (2.7X) were reported to be 0.04 ppm in muscle, 0.34 ppm in fat, ND in kidney, and 0.05 ppm in liver. At the next dosing level, 33 ppm (0.7X), residues were 0.017 ppm in liver, 0.07 ppm in fat, and ND (<0.05) in muscle and kidney. Although the registrant stated the limit of quantitation for the analytical method used in this study to detect tribuphos residues in animal tissues to be 0.05 ppm, they detected and reported residues below 0.05 ppm. Extrapolating from the 2.7X and 0.7X feeding levels to the 1X feeding level, residues of tribuphos in milk are expected to be as high as ND to 0.002 ppm in muscle (meat), 0.002 to 0.0025 ppm in liver (meat byproducts), and 0.10 to 0.13 ppm in fat. The existing tolerances for meat, meat byproducts (mbyp), and fat are all 0.02 ppm. The existing tolerance is adequate to cover residues of tribuphos expected for meat and mbyp. However, the existing tolerance for fat (0.02 ppm) appears to be too low. The existing tolerance for fat should be revoked and a tolerance of 0.15 ppm is recommended for tribuphos residues in fat.

CONCLUSION/RECOMMENDATION

In the absence of field trial data for residues of tribuphos on cotton gin byproducts, the above theoretical 1X dietary intake of tribuphos by animals indicates that existing tolerances for tribuphos residues in milk and fat are too low and should be revoked. Recommended tolerances for these commodities are 0.01 and 0.15 ppm, respectively. A tier I dietary exposure assessment using DRES should be run including these recommended tolerances for milk and fat commodities.

We recognize that the 1X dietary intake represents a conservative exposure assessment; however, because of the lack of data for cotton gin by products, further refinements to dietary burden calculations cannot be made at this time.

cc: RF, SF, List B File, Rob Travalligni (RCAB)
RDI: CAE 04/01/98, SAK 04/01/98

UNITED .TES ENVIRONMENTAL PROTECTION ENCY

Brian DeHart
Miles Inc.
P.O. Box 4913
8400 Hawthorne Road
Kansas City, MO 64120-0013

Subject: Tolerance Proposals for Tribuphos Based on Animal Feeding Study Review

Dear Mr. DeHart:

The Agency is forwarding an amended data evaluation record for the residue chemistry data submission, MRID 438216-01. The Agency has determined that 20% cotton gin byproduct should be included in the animal diets and that 200 ppm should be used as a default value for residues of tribuphos on cotton gin byproducts based on the residue data on cotton leaves from the metabolism study (MRID 438216-01). As part of the reregistration eligibility decision (RED) process, the published RED will require that the existing tolerances for tribuphos residues in milk and fat be revoked and that you petition the Agency for new tolerances for these commodities.

A copy of the review is enclosed. If you have any questions regarding this letter, call Tom Luminello at (703) 308-8075.

Sincerely,

Jack E. Housenger, Associate Director
Special Review and
Reregistration Division

cc: Catherine Eiden, HED

Enclosure

CONCURRENCES								
SYMBOL	7508-W							
SURNAME	Luminello	BAS						
DATE	6-12-98	6/12						

*U.S. Government Printing Office: 1992 — 620-856/4067

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R149580

Chemical: Tribuphos

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HED Records Reference Center
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